

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

KIMBERLY BELL,

Plaintiff,

V.

**COVIDIEN LP; COVIDIEN SALES LLC,
COVIDIEN HOLDING INC.; and
MEDTRONIC, INC.,**

Defendants.

**Civil Action No.
22-11465-FDS**

**MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO DISMISS**

SAYLOR, C.J.

This is a product-liability action involving a surgical stapler. Jurisdiction is based on diversity of citizenship.

Plaintiff Kimberly Bell alleges that defendants Covidien LP, Covidien Holding Inc., Covidien Sales LLC, and Medtronic, Inc. manufactured and marketed surgical stapler products that they knew to be dangerous. She alleges that she suffered lasting injuries after a stomach operation in which defendants' stapler failed to seal her stomach shut. The complaint asserts various product-liability, tort, and statutory claims against the defendants, and seeks compensatory damages.

Defendants have moved to dismiss the complaint on the ground that it fails to state a claim upon which relief can be granted. For the following reasons, the motion to dismiss will be granted in part and denied in part.

A. Factual Background

Unless otherwise noted, the following facts are as set forth in the complaint.

Kimberly Bell is a resident of North Carolina. (Compl. ¶ 3).

Covidien LP is a limited partnership. (*Id.* ¶ 4). According to the complaint, Covidien Holding Inc. is the sole partner of Covidien LP. (*Id.*).

Covidien Holding Inc. is a Delaware corporation with a principal place of business in Massachusetts. (*Id.* ¶ 5).

Covidien Sales LLC is a limited liability company. (*Id.* ¶ 4, 6). Covidien LP is the sole member of Covidien Sales LLC. (*Id.* ¶ 4).

Medtronic, Inc. is a Minnesota corporation with a principal place of business in Minnesota. (*Id.* ¶ 7).

The defendants are involved, to varying extents, in the “design, testing, manufacture, distribution, sales, marketing, regulatory management, and services” of the Covidien products at issue in this case. (*Id.* ¶¶ 4-7).

On September 11, 2019, Bell underwent a surgical procedure. (*Id.* ¶ 12, 15).¹ The procedure entails using surgical instruments to “cut, separate, and remove 80% of the patient’s stomach.” (*Id.* ¶ 13). A doctor can use a surgical stapler device to then “staple the open stomach shut.” (*Id.* ¶ 14). “A staple line failure occurs when a device fails to deploy staples that seal the stomach,” allowing stomach contents to empty into the patient’s body cavity. (*Id.*).

The complaint alleges that Bell’s physician, Peter Ng, used a Covidien Endo GIA stapler to “seal” and “separate a section of [her] stomach.” (*Id.* ¶ 15).² According to the complaint, Dr.

¹ The complaint describes the procedure as a “Laparoscopic Biliopancreatic Diversion with Duodenal Switch, and Laparoscopic Hiatal Hernial Repair.” (Compl. ¶ 12).

² The complaint later refers to Bell’s physician as “Dr. Ng Ahmed.” (Compl. ¶ 70).

Ng may have used three products manufactured by defendants: the “Endo GIA 45mm with Tri Staple Technology (EGIA45AVM)”;

the “Covidien Endo GIA 60mm with Tri Staple Technology (EGIA60AVM)”;

or the “Covidien Endo GIA Universal XL (EGIAUXL).” (*Id.* ¶ 44). Dr. Ng “performed the procedure consistent with standard medical practices,” and “used the surgical stapler in accordance with Defendants’ training materials and did not deviate from Defendants’ recommended Instructions for Use included in the device’s package insert.” (*Id.* ¶ 16). After the operation, Dr. Ng “performed a leak test, which appeared patent,” indicating that the “staple line [was] properly sealed.” (*Id.* ¶ 18).

The complaint alleges that Bell’s health worsened after the operation. On September 13, 2019, she “developed several episodes of nausea/vomiting and hypertension.” (*Id.* ¶ 22). On September 14, she “developed shortness of breath and worsening abdominal pain,” and a chest x-ray “revealed pulmonary edema.” (*Id.*). She was taken to the operating room, where an examination of the site of her surgery revealed a “‘small tear’ at the apex staples, measuring 5 mm.” (*Id.* ¶¶ 23-24). This leak led to “acute respiratory failure and pulmonary edema leading to septic shock.” (*Id.* ¶ 25). After her September 14 procedure, she remained in the hospital until October 11, 2019. (*Id.* ¶¶ 25-29).

The complaint alleges that because of Bell’s complications from surgery, she has “suffer[ed] significant injuries,” including “ongoing bowel issues,” “physical and emotional injuries,” “out of pocket expenses,” and “economic harm.” (*Id.* ¶¶ 33-35); (*see id.* ¶ 109 (listing various injuries, including “[a]cute [k]idney injury requiring dialysis” and “[o]ngoing medical treatment”)).

According to the complaint, from 2001 to 2019, reports indicated that hundreds of deaths and thousands of injuries, adverse events, and malfunctions were associated with surgical

staplers. (*Id.* ¶¶ 45-47). Defendants’ surgical staplers “frequently malfunctioned and were defective, compromising staple integrity and surgical procedures . . . even [when used] as instructed by Defendants in the device user manual.” (*Id.* ¶ 113).

The complaint essentially alleges that defendants “purposefully” circumvented surgical-device problem-reporting requirements to hide safety problems with their staplers. (*Id.* ¶ 69). In the 1990s, the FDA gave “manufacturers, the medical community, and the public” access to the Manufacturer and User Facility Device Experience Database (MAUDE), a database of medical-device adverse-event and product-problem reports. (*Id.* ¶ 67). According to the complaint, surgeons use MAUDE to “identify and analyze trends in malfunctions.” (*Id.* ¶ 68). The complaint alleges that defendants failed to submit 56,000 adverse-event reports on Covidien staplers to MAUDE, instead submitting those reports to the Alternative Summary Reporting Program (ASR). (*Id.* ¶¶ 69, 72). The complaint alleges that the ASR database was “hidden” and that defendants sent adverse-event reports to ASR rather than MAUDE “to keep the scope and seriousness of injuries related to surgical staplers hidden from surgeons and the public.” (*Id.* ¶¶ 48, 51).

According to the complaint, defendants’ choice to report adverse events to ASR and not MAUDE prevented surgeons from assessing the risks of using Covidien staplers. (*Id.* ¶ 79). The complaint characterizes this as a “knowledge gap,” in which surgeons were deprived of key information about adverse events, preventing them from making informed choices in stapler use—for example, in staple height or stapler model type. (*Id.* ¶¶ 62-63). The complaint alleges that Covidien’s decision to underreport adverse events related to its staplers “directly led to [Bell’s] physician electing to use a surgical stapler without full knowledge of all foreseeable risks.” (*Id.* ¶ 79).

The complaint further alleges that defendants failed to follow FDA regulations intended to promote safety. (*Id.* ¶¶ 80-91). According to the complaint, this allowed defendants to sell products that they knew “were defective, unreasonably dangerous, and not safe.” (*Id.* ¶ 90). It further alleges that in 2019, the FDA reclassified surgical staplers from Class I devices to Class II devices, “requiring a stricter approval process.” (*Id.* ¶ 93). The FDA’s decision was driven by “complications that can result from surgical stapler malfunctions” and “the high rate of reported incidents . . . associated with surgical staplers.” (*Id.* ¶¶ 95-96).

The complaint then alleges that several of defendants’ product lines were subject to recall before her injury. First, in 2016, the FDA announced a recall of the EGIAUXL Endo GIA Ultra Universal XL, on the basis that the “staplers fail to fire or partially fire” and that there were “reports of the instrument articulating level disengaging during use.” (*Id.* ¶ 103). That recall ended in July 2019, about two months before Bell’s surgery. (*Id.*). It also alleges that the two reloads that Bell’s surgeon used with his surgical stapler were part of the “Endo GIA Reloads with Tri-Staple Technology” product line, which had been subject to 22 recalls by the time of Bell’s surgery. (*Id.* ¶¶ 105, 107-08). It alleges that stapler reloads in this product line are “essentially variations of the same design,” and that “it is more likely than not that the design process, manufacturing processes, and quality control measures associated with these staplers are also shared.” (*Id.* ¶¶ 106, 108).

B. Procedural Background

Bell filed her complaint on September 9, 2022. The complaint as amended asserts five counts: breach of warranty for defective manufacture and design (Count 1); breach of warranty for failure to warn (Count 2); negligence (Count 3); negligent misrepresentation (Count 4); and deceptive trade practices in violation of Mass. Gen. Laws ch. 93A, § 2 (Count 5).

Defendants have moved to dismiss the complaint for failure to state a claim pursuant to

Fed. R. Civ. P. 12(b)(6).

II. Motion to Dismiss

A. Standard of Review

To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the “[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* at 555 (citations omitted). “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). When determining whether a complaint satisfies that standard, a court must assume the truth of all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences. *See Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). Dismissal is appropriate if the complaint fails to set forth “factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.” *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

B. Analysis

1. Choice of Law

At the onset, it is not clear which state’s substantive law should apply. Massachusetts courts use a “functional approach” to choice-of-law questions that relies in part on the RESTATEMENT (SECOND) OF CONFLICT OF LAWS (Am. L. Inst. 1971). *Cosme v. Whittin Mach. Works, Inc.*, 417 Mass. 643, 646 (1994). In personal injury cases, Section 146 of the Restatement suggests that the law of the state where the injury occurred should determine the

rights and liabilities of the parties unless another state has a more significant relationship to the underlying cause of action. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 146 (Am. L. Inst. 1971).

Somewhat oddly, neither the complaint nor plaintiff's response to the motion to dismiss specify where plaintiff's surgery took place. Defendants contend that the complaint should be dismissed whether Massachusetts or North Carolina law applies. Plaintiff contends that it is "inexplicabl[e]" that defendants have raised a choice-of-law issue, and cites only Massachusetts law in response to the motion to dismiss. (Pl.'s Resp. at 10).

Under the circumstances, the Court will apply Massachusetts law. A court "may accept the parties' agreement as to the choice of law without independent analysis of the governing rules." *Magarian v. Hawkins*, 321 F.3d 235, 238 n.4 (1st Cir. 2003). While the parties here have not formally agreed as to which state's substantive law should apply, both sides have cited Massachusetts law in their briefing, and neither contends that Massachusetts law should *not* apply. And certainly there is nothing obviously unfair about applying Massachusetts law to a lawsuit brought in Massachusetts against a Massachusetts-based company. *See Karter v. Pleasant View Gardens, Inc.*, 248 F. Supp. 3d 299, 306 n.2 (D. Mass. 2017) (concluding, after the plaintiff failed to specify the location of events in her complaint, that application of Massachusetts law was appropriate).

In Massachusetts product-liability cases, breach of the implied warranty of merchantability claims are functionally identical to strict-liability claims in other jurisdictions. *See Commonwealth v. Johnson Insulation*, 425 Mass. 650, 653-54 (1997). To succeed on a claim alleging breach of the implied warranty, the plaintiff must demonstrate (1) that the defendant manufactured or sold the product in question, (2) that a defect or unreasonably

dangerous condition existed that rendered the product not suitable for the ordinary uses for which the product was sold, (3) that she was using the product in a manner that the defendant intended or could reasonably have foreseen, and (4) that the defect or unreasonably dangerous condition was a legal cause of her injuries. *AcBel Polytech, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 928 F.3d 110, 116 (1st Cir. 2019). “A product may be defective and unreasonably dangerous because of a manufacturing defect, a design defect, or a warning defect, that is, a failure reasonably to warn of the product’s foreseeable risks of harm.” *Evans v. Lorillard Tobacco, Co.*, 465 Mass. 411, 422 (2013).

Here, the complaint alleges that defendants “designed, tested, manufactured, marketed, sold, and monitored a defective product family.” (Compl. ¶ 112). Specifically, the complaint alleges that the “Endo GIA stapler system used on Plaintiff was defective at the time of its sale or distribution.” (*Id.* ¶ 134).

2. Defective Manufacture and Design (Count 1)

Count 1 asserts claims for both manufacturing defects and design defects.

a. Manufacturing Defect

The first question is whether the complaint states a claim for a manufacturing defect.

A manufacturing defect may cause a product to be defective or unreasonably dangerous. *Evans*, 465 Mass. at 422. In a manufacturing-defect case, the factfinder must “compare the propensities of the product as sold with those which the product’s designer intended it to have” and determine “whether the deviation from the design rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes.” *Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978).

Here, the complaint fails to allege a plausible basis to conclude that the stapler used in plaintiff’s surgery deviated from its intended design. It alleges in general terms that defendants’

staplers suffered from “manufacturing defects,” and that the stapler used in plaintiff’s surgery was defective because of “an improper or incorrect manufacturing process.” (Compl. ¶¶ 88, 132). However, it pleads no facts about any particular manufacturing process, or a specific manufacturing defect, that actually led to the stapler’s failure. The complaint alleges myriad problems with the design of defendants’ staplers, (*e.g.*, *id.* ¶ 62), but those appear to be allegations related to the design of surgical staplers generally. And it makes no allegations about manufacturing issues with the specific product line used in defendant’s surgery.³

Plaintiff nonetheless contends that the FDA recalls cited in the complaint show that defendants’ staplers were defectively manufactured. An FDA recall of a specific product may, of course, be relevant to a manufacturing-defect claim. *See, e.g., Hunt v. Covidien LP*, 2022 WL 3566834, at *2 (D. Mass. Aug. 18, 2022) (finding that a contemporaneous FDA recall of the stapler handle used in the plaintiff’s surgery “provide[d] additional momentum” for a manufacturing defect claim). However, “[r]ecalls for different products do not suffice to allege that the stapler at issue also had a manufacturing defect.” *Corrigan v. Covidien LP*, 2022 WL 17094687, at *3 (D. Mass. Nov. 21, 2022).

Here, the complaint alleges that three products may have been used in plaintiff’s surgery. (Compl. ¶ 44). The recalls it describes, however, are for other stapler products. (*See id.* ¶¶ 103, 107). Although it alleges that “when a manufacturing problem plagues one Tri-Staple reload, it plagues them all,” that is not enough. (*Id.* ¶ 107). The fact that a specific manufacturing defect led to a recall of one product, without more, does not permit the conclusion that all related products had such a defect.

³ Plaintiff’s citation of *Sundaramurthy v. Abbott Vascular, Inc.*, 2022 WL 827235 (D. Mass. Mar. 18, 2022), is unavailing. In that case, the complaint alleged a specific flaw in the defendant’s manufacturing process—exposure of defendant’s products to excess heat. *Sundaramurthy*, 2022 WL 827235, at *3.

The complaint therefore fails to allege that the product as manufactured deviated from the manufacturer's intended design, and accordingly the manufacturing-defect claim will be dismissed.

b. Design Defect

The second question is whether the complaint states a claim for a design defect.

For a design-defect claim, a plaintiff must “prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm.” *Evans*, 465 Mass. at 428 (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 2 cmt. f (Am. L. Inst. 1998)). That inquiry requires the plaintiff to show that “the product in question could have been more safely designed, not that a different product was somehow safer.” *Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir. 2016).

Plaintiff contends that the complaint alleges specific design defects, pointing to paragraphs 62 and 104 of the amended complaint as examples. Paragraph 62 alleges that “there is no pause and no indicator of stapler success before its cutting blade activates.” (Compl. ¶ 62). It also alleges that “the selection of a stapler based on [various factors] can have a great effect on the clinical outcome. . . . [and that] very little guidance is provided by Defendants.” (*Id.*). It does not specify which of defendants' stapler products suffer from these defects, although it may be plausibly read to refer to all of them. Paragraph 62, while bare-bones at best, is minimally sufficient to allege a plausible design-defect claim.

Paragraph 104 alleges that plaintiff's “surgical team [] faced the full-fledged hazard of a stapler handle known to malfunction by failing to fire or partially firing staples.” (*Id.* ¶ 104). It is doubtful whether that paragraph is even minimally sufficient to allege a design-defect claim; the complaint makes that allegation in the context of a discussion of FDA recalls of surgical staplers and products manufactured by defendants generally. And the fact that other products

have malfunctioned or been recalled provides little insight into whether the specific stapler used in plaintiff's surgery was defective.⁴

In any event, the Court will not dismiss the design-defect claim at this stage of the proceedings. Whether plaintiff will actually be able to prove a design defect is a question that is better resolved on a full factual record.

3. Failure to Warn (Count 2)

The complaint alleges that defendants "failed to provide proper warnings or instructions to the products end users and patients like Plaintiff." (*Id.* ¶ 143). It further alleges that "[h]ad Plaintiff's physician known of the true failure rate of the Endo GIA stapler used on [her] during her surgery, he would not have performed the procedure and/or would not have used the [device]." (*Id.* ¶ 38).

"A manufacturer of a product has a duty to warn foreseeable users of dangers in the use of that product of which he knows or should have known." *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629, 631 (1986). A manufacturer may be held liable "even if the product does exactly what it is supposed to do, if it does not warn of the potential dangers inherent in the way a product is designed." *Laaperi v. Sears, Roebuck & Co.*, 787 F.2d 726, 729 (1st Cir. 1986). "It is not necessary that the product be negligently designed or manufactured." *Id.*

Under the "learned intermediary" doctrine, a medical-device manufacturer's obligation to warn of dangers associated with its product runs to the physician, not the patient. *Cottam v. CVS Pharm.*, 436 Mass. 316, 321 (2002); *Langlois v. American Med. Sys., Inc.*, 462 F. Supp. 3d 1, 4 (D. Mass. 2020). A plaintiff "carries the initial burden of producing sufficient evidence that the

⁴ The complaint also alleges in general terms that the stapler reloads (as opposed to the stapler handle) were defective. (*See id.* ¶ 117). However, the alleged design flaws described by the complaint appear to concern only stapler handles. While other reloads manufactured by defendants have been recalled, the complaint does not plead that the reloads used in plaintiff's surgery were recalled. (*Id.* ¶ 107). And the two alternative designs pleaded by the complaint relate to the stapler handle, not the reloads. (*Id.* ¶¶ 123-24).

defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known.” *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 81 (1st Cir. 1992). Factors relevant to determining the adequacy of a warning include

whether the warning adequately indicates the scope of the danger; whether the warning reasonably communicates the extent or seriousness of the harm that could result from misuse of the product; whether the physical aspects of the warning adequately alert a reasonably prudent person to the danger; and whether the means to convey the warning are adequate in the given circumstances.

Albright v. Boston Sci. Corp., 90 Mass. App. Ct. 213, 220 n.17 (2016) (quoting *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004).

Here, plaintiff contends that defendants failed to warn her physician of the products’ dangers in four ways: (1) by using the ASR program to conceal adverse event reports; (2) by failing to follow FDA regulations on product safety; (3) by failing to provide warnings, training, instruction, and education to surgeons on safe stapler use; and (4) by failing to timely recall their products. (*See* Pl.’s Opp. at 14).

Plaintiff contends that by using the ASR program, defendants concealed thousands of adverse event reports from surgeons and the public. (Compl. ¶¶ 67-79). It is true that the complaint concedes that defendants *did* report thousands of adverse events to the FDA as part of the ASR program. *Contra, e.g., Plourde v. Sorin Grp. USA, Inc.*, 23 F.4th 29, 34-37 (1st Cir. 2022) (discussing a failure-to-warn claim where the plaintiff alleged that the defendant had failed to report adverse events to the FDA). And the ASR data was publicly available before plaintiff’s September 2019 surgery. *See* Statement on Agency’s Efforts to Increase Transparency in Medical Device Reporting, U.S. Food and Drug Admin. (June 21, 2019) (publishing ASR data from 1999-2019) (cited in Compl. ¶ 50 n.14).

Nonetheless, whether defendants properly alerted plaintiff’s physician to the dangers of their products, and whether plaintiff’s physician justifiably relied on pre-June 2019 data, are

factual issues that the Court cannot resolve at this stage. The complaint further alleges that “[d]efendants intentionally failed to provide warnings regarding the potential for their staplers to malfunctions in the very manner that occurred during Plaintiff’s surgery,” and to “warn and inform surgeons of the potential for its staplers to malfunction in that manner, including all foreseeable use and misuse of the product.” (Compl. ¶ 118). And although the complaint does not identify dangers unique to the product used in plaintiff’s surgery, it does allege that improper use of surgical staplers may lead to complications. (*Id.* ¶ 62). Accordingly, while the complaint does not specifically allege what warning plaintiff’s physician was given as to the device’s dangers, it does allege that he was given minimal or no guidance as to the dangers identified by the complaint.

Under the circumstances, the complaint alleges sufficient facts to sustain a claim for breach of warranty based on failure to warn.

4. Negligence (Count 3)

Count 3 alleges that defendants “negligently designed, tested, manufactured, marketed, sold, monitored, and labeled the Endo GIA surgical stapler system.” (Compl. ¶ 146).

Count 3 does not allege one specific theory of negligence. Rather, the claims sound in negligent design, negligent manufacture, and negligent failure to warn. Under Massachusetts law, “[i]n most substantive aspects . . . the negligence and warranty inquiries are congruent.” *Gillispie v. Sears, Roebuck & Co.*, 386 F.3d 21, 26 (1st Cir. 2004). Here, they are entirely congruent. Count 3 is therefore entirely duplicative of Counts 1 and 2. The Court will therefore dismiss Count 3 except to the extent that it asserts a claim of negligent design and negligent failure to warn.

5. Negligent Misrepresentation (Count 4)

Count 4 alleges that defendants “negligently misrepresented to Plaintiff the safety of their

Endo GIA surgical stapler system by hiding adverse events in the ASR system.” (Compl. ¶ 158).

Under Massachusetts law, a negligent misrepresentation requires the plaintiff to show that the defendant

(1) in the course of his business, (2) supplie[d] false information for the guidance of others (3) in their business transactions, (4) causing and resulting in pecuniary loss to those others (5) by their justifiable reliance upon the information, and (6) with failure to exercise reasonable care or competence in obtaining or communicating the information.

Nota Constr. Corp. v. Keyes Assocs., Inc., 45 Mass. App. Ct. 15, 19-20 (1998).

Defendants contend that plaintiff’s claims are preempted by federal law. First, they argue that Count 4 should be read as a “fraud-on-the-FDA” claim, and that such a claim would be preempted under *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001). However, the complaint does not appear to allege that defendants provided *false* information to the FDA; rather, it alleges that defendants provided a vast amount of true information to the FDA, and that that information was kept from public view. Accordingly, the preemption concerns raised by the Supreme Court in *Buckman*—that the FDA is best positioned to enforce fraud against itself—do not appear to be present here. *See Buckman*, 531 U.S. at 348.

Second, defendants contend that “[i]f Plaintiff claims that the mere utilization of the then-FDA-authorized ASR system may constitute a negligent misrepresentation under state law, then [her] theory is expressly preempted by federal law,” citing 21 U.S.C. § 360k. Defendants do not elaborate further. At a minimum, therefore, the Court will not dismiss the claim on that basis in the absence of further explanation.

Defendants further contend that the complaint should be dismissed pursuant to Fed. R. Civ. P. 9(b). Rule 9(b) requires that a party alleging fraud or mistake “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Rule 9(b) applies to negligent misrepresentation claims that sound in fraud. *See, e.g., Paye v. Atrium*, 2023 WL

349894, at *11 (D. Mass. Jan. 20, 2023).

Count 4 alleges that defendants “made false statements regarding the true failure rate of their Endo GIA surgical stapler system” by “hiding adverse events in the ASR system,” “purely motivated by consideration of profit.” (Compl. ¶¶ 158-59). They allegedly “continued to market the Endo GIA surgical stapler system knowing the risks.” (*Id.* ¶ 163). Those allegations clearly invoke misrepresentation and deceit by defendants, and therefore Count 4 sounds in fraud and must be pleaded according to the standard of Rule 9(b). *See Ed Peters Jewelry Co., Inc. v. C & J Jewelry Co., Inc.*, 215 F.3d 182, 191 (1st Cir. 2000).

The complaint does not describe the “who, what, where, and when of the allegedly false or fraudulent representation.” *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004). Rather, it alleges that defendants submitted many reports over a twenty-year period to the FDA about many of their products. No particular misrepresentations are even mentioned. Accordingly, the negligent misrepresentation claim cannot survive the heightened pleading standard of Rule 9(b). *See Alternative Sys. Concepts*, 374 F.3d at 29.

6. Chapter 93A (Count 5)

Finally, Count 5 alleges that defendants “engaged [in] conduct that was in clear violation of [Mass. Gen. Laws ch. 93A, § 2] by the improper market and sale of the Endo GIA surgical stapler.” (Compl. ¶ 170). “Contrary to Defendants’ representations, the Endo GIA surgical stapler was not safe or effective when used for its intended purposes.” (*Id.* ¶ 172).

Chapter 93A prohibits “[u]nfair or deceptive acts or practices in the conduct of any trade or commerce.” Mass. Gen. Laws ch. 93A, § 2(a). A Chapter 93A claim must allege a practice that (1) is within “the penumbra of some common-law, statutory, or other established concept of unfairness,” (2) is “immoral, unethical, oppressive, or unscrupulous,” and (3) “causes substantial injury to consumers,” competitors, or other business entities. *Massachusetts Eye & Ear*

Infirmity v. QLT Phototherapeutics, Inc., 412 F.3d 215, 243 (1st Cir. 2005).

Defendants contend that the Chapter 93A claim should fail for two reasons. First, they contend that plaintiff “cannot show [a] causal connection between the alleged deceptive act and her injury.” (Defs.’ Mem. at 18). As discussed previously, whether defendants’ alleged use of the ASR system and failure to inform plaintiff’s physician of the risks of the stapler products used in her surgery is a factual issue that the Court will not resolve at this stage.

Second, defendants contend that plaintiff’s Chapter 93A claim is preempted by federal law. Defendants’ argument is identical to their preemption argument against Count 4, and is not briefed in sufficient detail to decide at this stage.

While there may be other potential issues as to the viability of the Chapter 93A claim, defendants have not raised them at this stage. Accordingly, the motion to dismiss Count 5 will be denied.

III. Conclusion

For the foregoing reasons, defendants’ motion to dismiss is GRANTED as to Count 4; as to Count 1, except to the extent that it alleges a design defect; as to Count 3, except to the extent that it alleges negligent design and failure to warn; and is otherwise DENIED.

So Ordered.

Dated: April 19, 2023

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court